DRAFT

Rhode Island Department of Health
Institutional Review Board (IRB)
Minutes of Meeting
September 2, 2004

In attendance: Utpala Bandy, Jay Buechner, John Fulton, Leonard Green (Vice-Chair), Ewa King (Alternate), Joann Lindenmayer (Chair), Sharon Marable (Alternate), Bruce McIntyre, Elizabeth Shelov, (Alternate) Vivian Weisman.

Absent but excused: Sally Zierler, Amy Zimmerman-Levitan (Alternate)

The Chair began the meeting at 9:35 AM.

The Chair asked Vivian Weisman and Bruce McIntyre, the primary and secondary reviewers (respectively) for proposal # 2004-08, Mercury, Lead and Cadmium Levels in Umbilical Cord Blood: a Pilot Study, to present their reports.

In the absence of the Principal Investigator, Dr. Greg Hayes, many of the Board's questions were directed to Board Member Ewa King. Dr. King was not expected to support nor defend any of the issues raised, but rather to provide any insights and information she may have regarding the design and/or protocols of the study.

The questions, issues and/concerns raised by Board members were:
1.What value(s) constitute an elevated mercury or cadmium level?
2. Are there thresholds that have been established for initiation of medical intervention?
4. Procedures for informed consent were lacking.
3. The study subjects constitute a very vulnerable population (mothers and newborns) and there is no mechanism established within the protocol for contacting the study subjects in the event of an elevated result.
4. The issue of the cord blood being a mixed sample of mother's and baby's blood and was this the best method of obtaining a sample?

The Board discussed what the communication from the Board to the Principal Investigator should contain. The following proposed language was formulated:

The Board can consider this study with the following elements incorporated into the study design:

1. Informed consent with a comprehensive description of the process;
2. Ability to link the results to the subjects
3. Release of results to the care-provider with information about credible available resources for referral;
4. No cost to the subject relative to the resources.

On a motion of Vivian Weisman and a second of John Fulton, all members of the Board (except one who voted to abstain) voted to charge the Board Chair with communicating these issues to the Principal Investigator and to request a written response.

The second item on the agenda was HEALTH IRB #2004-05, "The Development of Causal Learning," submitted by Dr. David Sobel of Brown University. Lenny Green and Elizabeth Shelov, primary and secondary reviewers, respectively, presented their reviews. The major concern noted by the Board was the manner in which the Principal Investigator proposes to recruit subjects, using Vital Records information provided to another investigator for a different purpose, and using this information to contact parents without explicitly stating the source of the information. Other, more minor concerns were also presented by the reviewers. A motion to disapprove this study was made and seconded, and the Board voted unanimously in favor of this motion.

At the request of the Chair, Attorney McIntyre reported on implications of the Open Meetings Laws for Investigators. He noted that, in his opinion, materials submitted by investigators are confidential. All meetings of the IRB are considered open, but if confidential information is to be discussed then that should be noted on the agenda and the meeting may be closed to the public for discussion of that information. Law proscribes the definition of what constitutes confidential information. For meetings that include both open and closed sessions, two sets of minutes should be written, one for the open session and another for the executive session. The Board discussed informing prospective researchers of the open meetings requirements on the IRB WebPages. However, prospective investigators should be provided a checkbox to request a closed meeting, but they should be required to describe the basis for the request and to explain the need for a closed meeting. The Chair should receive this request no less than two weeks prior to scheduled review of a proposal so that the agenda can be modified if necessary. The Board advised the Chair to look into practices of IRBs at the CDC and NIH for additional guidance in this matter.